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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
ZEMAN, ROBERT A	
ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 01/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/518,020	KAPLAN ET AL.	
	Examiner	Art Unit	
	Robert A. Zeman	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *14-36* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,37 and 38* is/are rejected.

7)☒ Claim(s) *13* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The response filed on 2-25-2002 is acknowledged. This application contains claims14-36 drawn to an invention non-elected with traverse in Paper No. 11. A complete reply to the final rejection must include cancellation of non-elected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01. Claims 1-38 are pending. Claims 14-36 remain withdrawn from consideration. Claims 1-14 and 37-38 are currently under examination.

Claim Rejections Withdrawn

The rejection of claim 13 under 35 U.S.C. 103(a) as being unpatentable over Gutnick et al. (U.S. Patent 4,311,829) in view of Fino (U.S. Patent 5,464,746) is withdrawn. Applicant's arguments have been fully considered and deemed persuasive.

Claim Rejections Maintained

35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 1-13 and 38 under 35 U.S.C. 112, second paragraph, as being rendered vague and indefinite by the use of the term "analog" is maintained for reasons of record.

Applicant argues:

1. The specification defines emulsan analogs as "structural analogs of the group of emulsans described above." on page 9, lines 13-14.

2. The specification further discloses the term "emulsan analog" as referring to "emulsans obtained from *A. calcoaceticus* mutants (e.g. transposon mutants) **which can be**, for example, emulsans obtained by mutants grown on ethanol as well as mutants grown on carbon sources other than ethanol" on page 9, lines 21-24.

Applicant's arguments have been fully considered and deemed non-persuasive.

Said term is still considered vague and indefinite since it does not clearly define what is considered an analog. The passages cited by Applicant merely list **possible** emulsan analogs. It is unclear what structure and/or function must be maintained in order for a given protein to be considered an "emulsan analog".

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection of claims 1-11 and 37-38 under 35 U.S.C. 102(b) as being anticipated by Gutnick et al. (U.S. Patent 4,311,829) is maintained for reasons of record.

Applicant argues:

1. The present invention relates to emulsan and emulsan analogs used as "adjuvants in immunization formulations".

2. The adjuvant activity of emulsan was exemplified the specification on page 39, line 1 through page 40, line 3.

3. The majority of the antibodies generated by Applicant's immunization composition were specific to the antigen component not the emulsan or emulsan analog.

4. Antigens are defined in the art as "foreign substances that induce specific immunity".

5. Adjuvants are defined in the art as "often needing to be administered in addition to the antigen in order to elicit an immune response to the antigen".

6. The emulsan or emulsan analog of the instant composition will generate a minor immune response in comparison to the antigen.

7. The emulsan in the composition disclosed by Gutnick et al. induced the predominant immune response, not the Freund's adjuvant.

Applicant's arguments have been fully considered and deemed non-persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the emulsan or emulsan analog will generate a minor immune response in comparison to the antigen) is not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The instant claims are drawn to compositions comprising an antigen and an emulsan or emulsan analog and hence are anticipated by Gutnick et al. which discloses a composition with said components.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 1 and 12 under 35 U.S.C. 103(a) as being unpatentable over Gutnick et al. (U.S. Patent 4,311,829) in view of Fino (U.S. Patent 5,464,746) is maintained for reasons of record.

Applicant argues:

1. For reasons outline above, Gutnick et al. does not teach or suggest an immunization that includes an emulsan or emulsan analog and an antigen.

2. Fino does not remedy the deficiencies of Gutnick et al. since Fino does not teach or suggest an immunization that includes an emulsan or emulsan analog and an antigen.

Applicant's arguments have been fully considered and deemed non-persuasive.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., the emulsan or emulsan analog will generate a minor immune response in comparison to the antigen) is not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The instant claims are drawn to compositions comprising an antigen (either viral, bacterial, parasitic or fungal) and an emulsan or emulsan analog. Since the combination of the cited references discloses a composition with said components the rejection is maintained.

Conclusion

No claim is allowed.

Claims 1-12 and 37-38 are rejected.

Claim 13 is objected to as being dependent on rejected claims.

Claim 13 is free of the art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert A. Zeman whose telephone number is (703) 608-7991. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (703) 308-3909. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Robert A. Zeman
January 23, 2003